8. REGULATIONS AND ADVISORIES

International guidelines for ammonia were not located. National and state regulations and guidelines pertinent to human exposure to ammonia are summarized in Table 8-1.

ATSDR has derived an acute-duration inhalation MRL of 1.7 ppm for ammonia based on a minimal LOAEL of 50 ppm for eye, nose, and throat irritation in a study with volunteers (Verberk et al. 1977). No NOAEL was identified in that study. An uncertainty factor of 30 (3 for the use of a minimal LOAEL and 10 to protect sensitive individuals) was applied to the LOAEL.

ATSDR has derived a chronic-duration inhalation MRL of 0.1 ppm for ammonia based on a NOAEL of 9.2 ppm for sense of smell, prevalence of respiratory symptoms (cough, bronchitis, wheeze, dyspnea, etc.), eye and throat irritation, and pulmonary function parameters in workers exposed for approximately 12 years in a soda ash plant (Holness et al. 1989). No LOAEL was defined in that study. The NOAEL was duration-adjusted, and divided by an uncertainty factor of 10 to protect sensitive individuals. A modifying factor of 3 was added for the lack of reproductive and developmental studies. This MRL supersedes the previous chronic inhalation MRL of 0.3 ppm derived in the 2002 draft for public comment version of this profile.

EPA derived an inhalation reference concentration (RfC) of 1E-1 mg/m^3 (0.14 ppm) for ammonia based on a NOAEL of 6.4 mg/m^3 (9.2 ppm) defined in the Holness et al. (1989) study (IRIS 2004). EPA used an uncertainty factor of 30 (10 to protect sensitive individuals and 3 for data base deficiencies).

Ammonia has not undergone a complete evaluation under EPA's IRIS program for evidence of human carcinogenic potential.

Ammonium ion is regulated by the Clean Water Effluent Guidelines for the following industrial point sources: ferroalloy manufacturing; fertilizer manufacturing; glass manufacturing; inorganic chemicals; iron and steelmaking; landfills; nonferrous metals manufacturing; nonferrous metals forming and metal powder; paper and paperboard; petroleum refining; pharmaceutical manufacturing; pulp, meat products; and transportation equipment cleaning (EPA 2002j).

The FDA (1973) determined that concentrations of ammonia and ammonium compounds normally present in food do not suggest a health risk; ammonia and ammonium ions are recognized to be integral components of normal metabolic processes. However, some restrictions have been placed on levels of ammonium salts allowable in processed of foods. Maximum allowable levels in processed foods are as follows: 0.04–3.2% ammonium bicarbonate in baked goods, grain, snack, foods and reconstituted vegetables; 2.0% ammonium carbonate in baked goods, gelatins and puddings; 0.001% ammonium chloride in baked goods and 0.8% in condiments and relishes; 0.6–0.8% ammonium hydroxide in baked goods, cheeses, gelatins and puddings; 0.01% monobasic ammonium phosphate in baked goods; and 1.1% dibasic ammonium phosphate in baked goods, 0.003% in nonalcoholic beverages, and 0.012% for condiments and relishes.

Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
INTERNATIONAL			
Guidelines:			
IARC	Carcinogenicity classification	No data	
WHO	Drinking water quality guideline		WHO 2002
	Ammonia		
	Threshold odor concentration	1.5 mg/L	
	Threshold taste concentration	35 mg/L	
	Health-based guideline	None proposed	
NATIONAL			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)		ACGIH 2001
	Ammonia	25 ppm	
	Ammonium chloride fume	10 mg/m^3	
	STEL (15-minute TWA)		ACGIH 2001
	Ammonia	35 ppm	
	Ammonia chloride fume	20 mg/m^3	
EPA	Accidental release prevention; toxic endpoint		EPA 2002b
	Ammonia (anhydrous)	0.14 mg/L	40CFR68, Appendix A
	Ammonia (>20% concentration)	0.14 mg/L	
	Regulated toxic substance for accidental release prevention under Section 112(r) of the Clean Air Act; threshold quantity		EPA 2002a
	Ammonia (anhydrous)	10,000 pounds	40CFR68.130, Table 1
	Ammonia (>20% concentration)	20,000 pounds	
	AEGL 1 (interim)	30 ppm	EPA 2004
NIOSH	REL (10-hour TWA)		NIOSH 2002b
	Ammonia	25 ppm	
	Ammonium chloride fume	10 mg/m^3	
	STEL (15-minute TWA)		NIOSH 2002b
	Ammonia	35 ppm	
	Ammonium chloride fume	20 mg/m^3	
	IDLH		NIOSH 2002b
	Ammonia	300 ppm	
	Ammonium chloride fume	No data	
OSHA	PEL (8-hour TWA) for general industry		OSHA 2002d 29CFR1910.1000, Table Z-1
	Ammonia	50 ppm	

Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
NATIONAL *(cont.)*			
OSHA	PEL (8-hour TWA) for construction industry		OSHA 2002c 29CFR1926.55, Appendix A
	Ammonia	50 ppm	
	PEL (8-hour TWA) for shipyard industry		OSHA 2002a 29CFR1915.1000
	Ammonia	50 ppm	
	Highly hazardous chemical, toxic, and reactive for general industry; threshold quantity[a]		OSHA 2002e 29CFR1910.119, Appendix A
	Ammonia	10,000 pounds	
	Ammonia solutions (>44% of ammonia by weight)	15,000 pounds	
	Highly hazardous chemical, toxic, and reactive for construction industry; threshold quantity[a]		OSHA 2002f 29CFR1926.64, Appendix A
	Ammonia	10,000 pounds	
	Ammonia solutions (>44% of ammonia by weight)	15,000 pounds	
	Occupational safety and health standards; storage and handling of anhydrous ammonia		OSHA 2002g 29CFR1910.111
	Occupations involved in agriculture that are particularly hazardous for the employment of children below the age of 16	Transporting, transferring, or applying anhydrous ammonia	OSHA 1998 29CFR570.71(a)(11)
	Safety and health regulations for construction; blasting and use of explosives; common blasting agent is a mixture of ammonium nitrate and carbonaceous combustibles		OSHA 2002b 29CFR1926.914(e)
b. Water			
EPA	Hazardous substance designated pursuant to Section 311(b)(2)(A) of the Clean Water Act		EPA 2002h 40CFR116.4, Table A
	Ammonia		
	Ammonium chloride		
	Ammonium fluoride		
	Ammonium hydroxide		
EPA	Reportable quantity of hazardous substances designated pursuant to Section 311 of the Clean Water Act		EPA 2002i 40CFR117.3
	Ammonia	100 pounds	
	Ammonium chloride	5,000 pounds	
	Ammonium fluoride	100 pounds	
	Ammonium hydroxide	1,000 pounds	

Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
NATIONAL *(cont.)*			
USC	Assurances of availability of adequate supplies of chemicals necessary for treatment of water	Ammonia	USC 2002a 42USC300j
c. Food			
EPA	Residues from ammonium chloride, ammonium hydroxide, and ammonium sulfate are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally inactive) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest		EPA 2002e 40CFR180.1001(c)
	Ammonium nitrate is exempt from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only		EPA 2002e 40CFR180.1001(d)
	The fungicide ammonia is exempted from the requirement of a tolerance when used after harvest on the raw agricultural commodities grapefruit, lemons, oranges, and corn grain for feed use only		EPA 2002f 40CFR180.1003
FDA	Direct food substances affirmed as generally recognized as safe	Ammonium chloride	FDA 2001a 21CFR184.1138
	Direct food substances affirmed as generally recognized as safe	Ammonium hydroxide	FDA 2001b 21CFR184.1139
FDA	Direct food substances affirmed as generally recognized as safe	Ammonium sulfate	FDA 2001c 21CFR184.1143
	Drug products containing certain active ingredients offered over-the-counter	Ammonium chloride	FDA 2001d 21CFR310.545(a)
	Expectorant drug product	Ammonia solution	
	Fever blister and cold sore treatment drug product	Ammonia solution and Ammonium hydroxide	
	Insect bite and sting drug products	Ammonium hydroxide	
	Food additives permitted in feed and drinking water of animals	Anhydrous ammonia	FDA 2001e 21CFR573.180
	Substance generally recognized as safe when used in accordance with good manufacturing or feeding practices	Ammonium hydroxide	FDA 2001f 21CFR582.1139

Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
NATIONAL *(cont.)*			
	Substance generally recognized as safe when used in accordance with good manufacturing or feeding practices	Ammonium sulfate	FDA 2001g 21CFR582.1143
d. Other			
CPSC	Federal Caustic Poison Act		CPSC 2001
	Ammonia water and any preparation containing free or chemically uncombined ammonia, including ammonium hydroxide and “hartshorn”, in a concentration of 5% or more		16CFR1500.129(1)
EPA	Ammonia		IRIS 2004
	Carcinogenicity classification	No data	
	RfC	$1x10^{-1}$ mg/m^3	
	RfD	No data	
	CERCLA hazardous substance designated pursuant to Section 311(b)(4) of the Clean Water Act		EPA 2002d
	Reportable quantity		40CFR302.4(a)
	Ammonia	100 pounds	
	Ammonium chloride	5,000 pounds	
	Ammonium fluoride	100 pounds	
	Ammonium hydroxide	1,000 pounds	
EPA	Extremely hazardous substance		EPA 2002c
	Ammonia		40CFR355,
	Reportable quantity	100 pounds	Appendix A
	Threshold planning quantity	500 pounds	
	Toxic chemical release reporting; Community right-to-know; effective date for reporting		EPA 2002g
	Ammonia[b]	01/01/87	40CFR372.65(a)
	Ammonium nitrate (solution)	01/01/87[c]	
USC	Imposition of Superfund tax on any taxable chemical sold by the manufacturer, producer, or importer		USC 2002d
	Ammonia	$2.64 per ton	26USC4661
	Refund or credit of Superfund tax paid when ammonia is used as a fertilizer		USC 2002b 26USC4662
	Superfund taxable substance	Ammonium nitrate	USC 2002c 26USC4672
STATE			
Regulations and Guidelines:			
a. Air		No data	

Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
STATE *(cont.)*			
b. Water		No data	
c. Food		No data	
d. Other		No data	
Florida	Toxic substance		BLR 2002
	Ammonia		
	Ammonium chloride		
	Ammonium fluoride		
	Ammonium nitrate		
	Ammonium sulfate		
Massachusetts	Hazardous substance		BLR 2002
	Ammonia		
	Ammonium chloride		
	Ammonium fluoride		
	Ammonium hydroxide		
	Ammonium nitrate		
	Ammonium sulfate		
Minnesota	Hazardous substance		BLR 2002
	Ammonia		
	Ammonium chloride, fume		
New Jersey	Hazardous substance		BLR 2002
	Ammonia		
New York	Hazardous substance		BLR 2002
	Ammonia		
	Ammonium chloride		
	Ammonium fluoride		
	Ammonium hydroxide		
Pennsylvania	Hazardous substance		BLR 2002
	Ammonia		
	Ammonium chloride		
	Ammonium fluoride		
	Ammonium hydroxide		

[a]Potential for a catastrophic event at or above the threshold quantity.
[b]Ammonia: includes anhydrous ammonia, aqueous ammonia from water, dissociable ammonium salts, and other sources; 10% of total aqueous ammonia is reportable under this listing.
[c]Ammonium nitrate (solution) is removed from this listing; the removal is effective 07/02/95, for the 1995 reporting year.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline value: BLR = Business & Legal Reports, Inc. CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CPSC = Consumer Protection Safety Commission; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life and health; IRIS = Integrated Risk Information System; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; ppm = parts per million; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TLV = threshold limit value; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization